

REMARKS

Applicants would first like to thank Examiner Tran for granting the telephonic interview of January 11, 2003, in which the pending rejections under 35 U.S.C. §102 were discussed. During the interview, Examiner Tran and the applicant's attorney came to an understanding as to claim amendments and statements that would help place the claims in condition for allowance.

Claims 1 and 3-63 are currently pending in this application. Claims 1 and 3-18 are under examination in this application. Claim 1 has been amended without prejudice. Claims 17-63 are cancelled by this Amendment to make this Request for Consideration a complete reply to the Final Office Action dated October 21, 2002. Applicants do not believe that additional search is required for consideration of the amended claims.

In view of the forgoing amendments and following remarks, applicants respectfully request reconsideration of the application and claims and submit that the application is in condition for allowance.

Amendment of the claims is supported by the application as filed, does not add new matter, and is otherwise proper. Applicants respectfully request entry of this amendment in its entirety.

I. Objection to the Drawings

Applicant would like to thank the Examiner for noting that the proposed drawings have been approved. However, the Final Office Action of October 21, 2002, noted that corrected drawings were required. As acknowledged by the Examiner in the telephone conversation on November 1, 2002, between the Examiner and applicants' attorney, Bernard P. Friedrichsen, corrected drawings were previously submitted along with applicants' Amendment and Response dated July 8, 2002, and applicants' Letter Regarding Changes to Drawings. Specifically, a corrected Formal Drawing that included the reference numeral 33 was provided along with a drawing showing the addition of "33" in red. Accordingly, no further corrected drawings should be required in response to the Final Office Action.

II. Withdrawn Objections and Rejections

Applicants thank the Examiner for acknowledging that the objections and rejections under the second paragraph of 35 USC 112 have been withdrawn. Applicants additionally thank the Examiner for acknowledging that the rejections under the judicially created doctrine of obviousness-type double patenting have been withdrawn.

III. Rejection of Claims Under 35 U.S.C. §102

In the Office Action, the rejection of claims 1, 3-7, 14 and 16 was maintained "as being anticipated by Abbott *et al.* (U.S. Patent 6,284,197 B1)." According to the MPEP, a "claim is anticipated only if each and every element as set forth in the claim is found... in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the... claim." MPEP § 2131 (citations omitted). However, Abbott *et al.* fail to disclose each and every element of the claimed invention. Specifically, Abbott *et al.* fail to teach providing a substrate that has depressions "selected in size to... be occupied by the selected pathogen[.]" Abbott *et al.* also do not disclose that any pathogen bound to the substrate "at least partially occupies the depression" or that the bound pathogen occupying the depression disorders liquid crystal that is thereafter applied.

Because Abbott *et al.* fails to teach each and every element of the claimed invention, it cannot anticipate the claimed invention and applicants respectfully request the Examiner withdraw this rejection.

Regarding claim 16, applicants respectfully note that cited portions of Abbott *et al.* do not teach that "substantially all the binding agent is located in the depressions of the detection region." The Office Action cites col. 40, lines 42-44 of Abbott *et al.* for the proposition that "[t]he binding agents are located in the depression of the detection region"; however, this passage does not state that substantially all of the binding agent is in the depressions. Accordingly, because the cited reference does not teach each and every feature of claim 16, it cannot anticipate this claim and applicants respectfully request the Examiner withdraw this rejection.

The rejection of claims 1, 3-6, and 14 "as being anticipated by Abbott *et al.* (U.S. Patent 6,277,489 B1)" was also maintained from the previous Office Action. As above, Abbott *et al.* fail to teach each and every element of independent claim 1. Abbott *et*

al. fail to teach providing a substrate that has depressions "selected in size to... be occupied by the selected pathogen[.]" Abbott *et al.* also do not disclose that any pathogen bound to the substrate "at least partially occupies the depression" or that the bound pathogen occupying the depression disorders liquid crystal that is thereafter applied. Because Abbott *et al.*, U.S. Patent No. 6,277,489, fails to teach each and every element of the claimed invention, it cannot anticipate the claimed invention and applicants respectfully request the Examiner withdraw this rejection.

Claims 1, 3-7 and 14 were also "rejected under 35 U.S.C. 102(f) because the Applicant did not invent the claimed subject matter." As discussed above, U.S. Patent 6,284,197 does not disclose each and every element of the claimed invention and cannot anticipate the rejected claims. Accordingly, applicants respectfully request the anticipation rejections be withdrawn.

IV. Rejection of Claims Under 35 U.S.C. § 103

In the Office Action, claims 8-9 were again "rejected under 35 U.S.C. 103(a) as being obvious over Abbott *et al.* (U.S. Patent 6,284,197 B1) in view of Leavitt *et al.* (U.S. Patent 5,712,103) because "Leavitt *et al.* teaches a method step where an assay involves an antigen or antibody (immunoglobulin) immobilized on a substrate and to minimize non-specific binding by coating the substrate with bovine serum albumin."

As stated in the MPEP, "[t]o establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03. However, as discussed above, Abbott *et al.* fails to teach or suggest all the elements of the claimed invention. Leavitt *et al.* is only cited for the proposition that "proteinaceous materials such as bovine serum albumin, are commonly used to coat a solid substrate to reduce non-specific binding." Therefore, Leavitt *et al.* fail to make up for deficiencies of Abbott *et al.* and their combination cannot state a *prima facie* case of obviousness.

In the office action, claims 10-13 and 15 were again "rejected under 35 U.S.C. 103(a) as being obvious over Abbott *et al.* (U.S. Patent 6,284,197 B1)." However, as discussed above, Abbott *et al.* fails to teach or suggest all the elements of the claimed invention. Specifically, Abbott *et al.* fail to teach or suggest providing a substrate that has

depressions "selected in size to... be occupied by the selected pathogen[.]" Abbott *et al.* also do not teach or suggest that any pathogen bound to the substrate "at least partially occupies the depression" or that the bound pathogen occupying the depression disorders liquid crystal that is thereafter applied. Accordingly, Abbott *et al.* alone cannot state a proper *prima facie* case of obviousness.

In the office action, claims 17-18 were again "rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott *et al.* (U.S. Patent 6,284,197 B1) in view of Leavitt *et al.* (U.S. Patent No. 5,712,103) as applied to claims 8-9 above, and further in view of Chagnon *et al.* (U.S. Patent No. 4,628,037). Claims 17 and 18 have been cancelled rendering the rejection moot.

Accordingly, the references cited in the Office Action fail to teach or suggest all of the claim elements of the present invention and applicants respectfully request the Examiner withdraw these rejections.

CONCLUSION

In view of the above remarks and amendments, it is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

Respectfully submitted,

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By 

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Version with markings to show changes made

1. A method for use in detecting the presence of a selected microscopic pathogen in a sample comprising:

(a) providing a substrate having a detection region thereon comprising a surface comprising microstructures including depressions having width and depth, wherein the [of] width and depth of the depressions are selected in size[d] to:

(i) align a liquid crystal material in contact therewith; and

(ii) [wherein the depressions are of a size sufficient to] be occupied by the selected pathogen;

(b) treating the surface of the detection region to provide a layer thereon that blocks non-specific binding of pathogens to the surface and that includes a binding agent that specifically binds the selected pathogen to be detected:

(c) applying a sample to be tested for the presence of the specific pathogen to the surface of the detection region of the substrate, wherein when the specific pathogen is present in the sample the specific pathogen binds to the binding agent and at least partially occupies the depression; and

(d) thereafter applying the liquid crystal material to the detection region that will be aligned by the microstructures on the surface of the substrate in the absence of binding pathogen particles to the surface of the substrate, wherein[by] the presence of the selected pathogen bound to the binding agent and at least partially occupying the depression [in the sample] will be manifested by a visually observable disordering of the liquid crystal material[caused by the pathogen particles bound to the substrate].